



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0310 and EPA-HQ-OPP-2021-0529; FRL-10884-01-OCSP]

Fluazifop-P-butyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluazifop-P-butyl in or on multiple commodities which are identified and discussed later in this document. The Interregional Research Project Number 4 (IR-4) and Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The dockets for this action, identified by docket identification (ID) numbers EPA-HQ-OPP-2021-0310 and EPA-HQ-OPP-2021-0529, are available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. For the latest status information on EPA/DC services, docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID numbers EPA-HQ-OPP-2021-0310 and EPA-HQ-OPP-2021-0529 in the subject line on the first page of your

submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID numbers EPA-HQ-OPP-2021-0310 and EPA-HQ-OPP-2021-0529, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of August 24, 2021 (86 FR 47275) (FRL-8792-02-OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP1E8909) by IR-4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested that 40 CFR 180.411 be amended by establishing tolerances for residues of the herbicide fluazifop-P-butyl, butyl(R)-

2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, in or on berry, low growing, subgroup 13–07G at 3 parts per million (ppm); Brassica, leafy greens, subgroup 4–16B at 15 ppm; chive, dried leaves at 40 ppm; fruit, citrus, group 10–10 at 0.03 ppm; fruit, stone, group 12–12 at 0.05 ppm; leaf petiole vegetable subgroup 22B at 3 ppm; onion, green, subgroup 3–07B at 4 ppm; papaya at 0.01 ppm; and vegetable, brassica, head and stem, group 5–16 at 30 ppm. Upon the establishment of these tolerances, IR-4 requested that EPA remove the existing tolerances in 40 CFR 180.411 for residues of fluazifop-P-butyl in or on fruit, citrus, group 10 at 0.03 ppm; fruit, stone at 0.05 ppm; onion, green at 1.5 ppm; rhubarb at 0.50 ppm; and strawberry at 3.0 ppm. That document referenced a summary of the petition prepared by IR-4, the petitioner, which is available in the docket, <https://www.regulations.gov> in docket ID EPA-HQ-OPP-2021-0310. A comment was received on the notice of filing. EPA's response to the comment is discussed in Unit IV.C.

In the *Federal Register* of November 17, 2022 (87 FR 68959) (FRL-9410-07-OCSP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP0F8890) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180 be amended by establishing tolerances for inadvertent residues of fluazifop-P-butyl metabolite 5-(Trifluoromethyl)-2-Pyridone (TFP) in or on the raw agricultural commodities corn forage at 0.01 ppm; corn grain at 0.01 ppm; and corn stover at 0.015 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, <https://www.regulations.gov> in docket ID EPA-HQ-OPP-2021-0529. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the levels at which tolerances are being established for some commodities and has adjusted the commodity definition for others. The reasons for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluazifop-P-butyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluazifop-P-butyl follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemaking of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking and republishing the same sections is unnecessary. EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a tolerance rulemaking for fluazifop-P-butyl in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm results from aggregate exposure to fluazifop-P-butyl and established tolerances for residues of

that chemical. EPA is incorporating previously published sections from this rulemaking as described further in this rulemaking, as they remain unchanged.

Toxicological profile. For a discussion of the Toxicological Profile of fluazifop-P-butyl, see Unit III.A. of the September 27, 2017, final rulemaking (82 FR 44936) (FRL-9966-67).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for fluazifop-P-butyl used for human risk assessment, please reference Unit III.B. of the September 27, 2017, final rulemaking. As explained in the Food Quality Protection Act (FQPA) safety factor section in this rule, the safety factor for inhalation exposure has decreased from 10X to 1X so the level of concern for short term inhalation exposures is now 100 rather than 1,000 like it was in 2017.

Exposure assessment. Much of the exposure assessment remains the same although updates have occurred to accommodate the exposures from the petitioned-for tolerances. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, please reference Unit III.C of the September 27, 2017, final rulemaking.

EPA's dietary exposure assessments have been updated to include the additional exposure from the proposed new uses and indirect/inadvertent residues of fluazifop-P-butyl on the commodities identified in this action and were conducted using the Dietary Exposure Evaluation Model software using the Food Commodity Intake Database (DEEM-FCID) Version 4.02, which uses the 2005 – 2010 food consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The acute dietary exposure assessment assumed tolerance-level residues for plant commodities, anticipated residues for livestock commodities, 100 percent crop treated (PCT) and default processing factors. The chronic dietary exposure assessment was based on mean residue levels from crop field trials, average PCT estimates for registered uses of fluazifop-P-butyl, projected PCT estimates for proposed new uses on broccoli and cauliflower,

and experimentally determined processing factors where available. For both the acute and chronic exposure assessments, the residues were adjusted to account for additional metabolites of concern.

Anticipated residue and percent crop treated (PCT) information. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require, pursuant to FFDCA section 408(f)(1), that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the PCT for existing uses as follows:

For the acute dietary analysis, 100% crop treated was assumed for all crops. The average percent crop treated estimates were used in the chronic dietary risk assessments for the following

crops that are currently registered for fluazifop-P-butyl: apricots 1%; asparagus 1%; carrots 25%; cherries 1%; cotton 1%; dry beans/peas 1%; garlic 5%; grapefruit 5%; grapes 1%; lemons 1%; onions 10%; oranges 1%; peaches 2.5%; peanuts 1%; plums/prunes 1%; potatoes 1%, soybeans 2.5%; strawberries 1%; sugar beets 1%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use 1% or 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses 2.5% as the maximum PCT.

In addition, projected PCT was used for the proposed uses on broccoli (30% PCT) and cauliflower (45% PCT); 100 PCT was assumed for the other proposed uses. EPA assumes the percent crop treated for a new use (PCT_n) is unlikely to exceed that of the PCT of the dominant pesticide (*i.e.*, the one with the greatest PCT) used on that crop over the three most recent years of available data, which spans from 2016 - 2020. Comparisons are only made among pesticides of the same pesticide types (*e.g.*, the dominant insecticide on the crop is selected for comparison with a new insecticide). The PCTs included in the analysis may be for the same pesticide or for different pesticides since the same or different pesticides may dominate each year. Typically, EPA uses USDA/NASS as the source for raw PCT data because it is publicly available and does

not have to be calculated from available data sources. When USDA/NASS does not survey a specific use site, EPA uses other appropriate public data or private market research to calculate the PCT_n.

The average PCT of the market leader(s) is appropriate for use in the chronic dietary risk assessment because it represents exposure over time. This method of estimating a PCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial five years of actual use. The predominant factors that bear on whether the estimated PCT_n could be exceeded are (1) the extent of pest pressure on the crops in question; (2) the pest spectrum of the new pesticide in comparison with the market; and (3) resistance concerns with the market leaders. EPA has examined the relevant data and concludes that it is unlikely that the actual PCT with fluazifop-P-butyl on broccoli and cauliflower will exceed the PCT_n within the next 5 years.

The Agency believes that the three conditions discussed in this section have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which fluazifop-P-butyl may be applied in a particular area.

Dietary exposure from drinking water. The recommended estimated drinking water concentrations in the September 27, 2017, final rulemaking remain valid and are considered protective of potential drinking water residue levels anticipated from the proposed new uses.

Non-occupational exposure. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

There are no new proposed residential uses. Fluazifop-P-butyl is currently registered for use on lawns/turf (including home lawns and golf courses) and ornamentals in residential settings that could result in residential exposures. For these currently registered uses of fluazifop-P-butyl, there are no residential (handler and post-application) risk estimates of concern. The residential exposure scenarios recommended for aggregate risk assessment of fluazifop-P-butyl are dermal and inhalation handler exposure from applications to gardens/trees using a backpack sprayer for adults and combined dermal plus hand-to-mouth post-application exposure from high-contact activities on treated turf for children 1 to less than 2 years old.

Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fluazifop-P-butyl and any other substances, and fluazifop-P-butyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fluazifop-P-butyl has a common mechanism of toxicity with other substances.

Safety factor for infants and children. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of

threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Prenatal and postnatal sensitivity. Increased quantitative sensitivity of the fetus was observed in the rat developmental studies in which no maternal toxicity was observed. Developmental toxicity in the rat was generally related to incomplete and/or delayed ossification. At higher doses, decreased fetal body weight and an increased incidence of diaphragmatic hernia were observed. In the rabbit, maternal and developmental toxicity were observed at the same dose. Maternal toxicity included abortions, weight loss, and death, while fetal toxicity included abortions, skeletal effects, and fetuses that were small and/or had cloudy eyes. In the rat reproduction and fertility study, maternal toxicity (increased liver weight, bile duct hyperplasia, and geriatric nephropathy) and offspring toxicity (decreased pup viability, decreased pup body weight, and hydronephrosis) were observed at the same dose level, and decreased female fertility was observed at the highest dose.

Conclusion. The FQPA Safety Factor is being retained at 10X for the acute dietary assessment, as an uncertainty factor for lowest observed adverse effect level (LOAEL) to no observed adverse effect level (NOAEL) extrapolation (UF_L) due to lack of a NOAEL in the acute neurotoxicity study from which the risk assessment endpoint was chosen. For the remaining applicable exposure scenarios, EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- The toxicity database is adequate for characterizing pre- and postnatal risk for infants and children. The database includes five rat developmental toxicity studies, two rabbit

developmental toxicity studies, a rat reproduction study, acute and subchronic neurotoxicity studies, a delayed neurotoxicity study, and an immunotoxicity study. EPA previously retained the 10X FQPA SF when assessing short-term inhalation exposures due to a lack of a subchronic inhalation study; however, EPA has determined that the subchronic inhalation study is no longer necessary to assess risk to infants and children because of the low potential for volatilization, the low acute inhalation toxicity of fluazifop, the fact that the respiratory system is not a target organ, and the fact that the use of the oral point of departure (POD) results in margins of exposure (MOEs) greater than 1,000 for all residential handler scenarios. Thus, the available data is sufficient to ensure that the 1X will be protective.

- The endpoints selected are protective of any potential neurotoxic effects.
- There was no indication of increased fetal or offspring susceptibility compared to maternal toxicity in the rabbit developmental or rat reproduction studies. Quantitative susceptibility of the fetus was noted in the rat developmental studies. However, the selected PODs are protective for these effects. Therefore, the degree of concern is low.
- There is no residual uncertainty in the exposure database for fluazifop-P-butyl with respect to dietary (food and water) and residential (turf and ornamental use) exposure. The dietary food exposure assessments include assumptions that result in high-end estimates of dietary food exposure. Also included in the assessments are modeled drinking water estimates that are designed to be protective of the highest potential residue levels in drinking water from among a range of exposure scenarios. In addition, the residential exposure assessment was conducted based on the conservative assumptions for assessing post-application exposure of children found in the Residential Standard Operating Procedures and chemical-specific data such that residential exposure and risk will not be underestimated.

Aggregate risks and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population adjusted dose (aPAD) and the chronic population adjusted dose (cPAD). Short-,

intermediate-, and chronic term aggregate risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure to ensure that an adequate MOE exists.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 38% of the aPAD for children 1 to 2 years old, the group with the highest exposure. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 66% of the cPAD for children 1 to 2 years old, the most highly exposed group. Fluazifop-P-butyl is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluazifop-P-butyl. The short-term aggregate MOE for adults is 200 and for children 1 to <2 years old is 480. These are greater than the level of concern of 100 and are not of concern. All residential exposures are anticipated to be short-term in duration; thus, an intermediate-term aggregate risk assessment is not required.

Fluazifop-P-butyl is classified as "Not Likely to be Carcinogenic to Humans"; therefore, EPA does not expect fluazifop-P-butyl exposures to pose an aggregate cancer risk.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to fluazifop-P-butyl residues. More detailed information on this action can be found in the document "Fluazifop-P-butyl. Human Health Risk Assessment for Proposed Uses and/or Tolerances on Brassica, leafy greens (subgroup 4-16B), Vegetable, Brassica, head and stem (group 5-16), Leaf petiole vegetable (subgroup 22B), Chive, dried leaves, and Papaya; Crop group expansions to Onion, green, subgroup 3-07B and Berry, low growing, subgroup 13-07G; Crop group conversions to Fruit, citrus, group 10-10 and Fruit, stone, group 12-12; and Rotational Field Corn" in docket ID EPA-HQ-OPP-2021-0310 and EPA-HQ-OPP-2021-0529.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (High Performance Liquid Chromatography/Ultraviolet Spectrometry (HPLC/UV)) is available to enforce the tolerance expression for crops. In addition, method GRM044.09A, a liquid chromatography and tandem mass spectroscopy (LC/MS/MS) method, is available for the enforcement of 5-(Trifluoromethyl)-2-Pyridone (TFP) residues in/on rotational crops.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The tolerances for fruit, citrus, group 10-10 and fruit, stone, group 12-12 are being harmonized with the respective Codex MRLs at 0.01 ppm. No Codex MRLs have been established for residues of fluazifop-P-butyl in or on the other commodities in this rulemaking.

C. Response to Comments

One comment was received on the notice of filing, which opposed EPA establishing the requested tolerances and objected to the use of pesticides on crops. Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerances are safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that the fluazifop-P-butyl tolerances are safe. The

commenter has provided no information indicating that a safety determination cannot be supported.

D. Revisions to Petitioned-For Tolerances

The tolerance levels for fruit, citrus, group 10-10 and fruit, stone, group 12-12 are being set at the method limit of quantitation (LOQ) of the analytical method, 0.01 ppm, to harmonize with the Codex MRLs for these crop groups. The Codex MRL for citrus and stone fruit is established at 0.01 ppm, reflecting the LOQ of the enforcement method and no detects in the field trial data. The established U.S. tolerances of 0.03 ppm for fruit, citrus, group 10 and 0.05 ppm for fruit, stone reflect the highest LOQ reported in the respective field trials. As sprays are directed to weeds at the base of the trees or vines, residue translocation into tree/vine fruit is not expected, and suitably sensitive analytical enforcement methods are available. Therefore, a tolerance of 0.01 ppm for groups 10-10 and 12-12 is not expected to lead to violative residues.

IR-4 requested a tolerance of 4 ppm for onion, green, subgroup 3-07B based partly on the established tolerance of 1.5 ppm for onion, green and field trial residue data on chives, fresh leaves that supports a tolerance of 4 ppm. Because green onion is the representative commodity for onion, green, subgroup 3-07B, EPA is establishing the tolerance for subgroup 3-07B at 1.5 ppm and is establishing a tolerance for chives, fresh leaves at 4 ppm based on the chives field trial residue data. In addition, EPA corrected the commodity definitions for the field corn commodities to reflect standard Agency terminology.

E. International Trade Considerations

In this rule, EPA is establishing tolerances for fluazifop-P-butyl residues in or on fruit, citrus, group 10-10 and fruit, stone, group 12-12 at 0.01 ppm that are lower than the current tolerances of 0.03 ppm for fruit, citrus, group 10 and 0.05 ppm for fruit, stone. For the reasons explained in Unit IV.D, the Agency believes these revised, lower tolerances are appropriate based on available residue data and analytical methods.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of the changes to these tolerances in order to satisfy its obligations under the Agreement. In addition, the SPS Agreement requires that Members provide a "reasonable interval" between the publication of a regulation subject to the Agreement and its entry into force to allow time for producers in exporting Member countries to adapt to the new requirement. Accordingly, EPA is retaining the existing tolerances for citrus group 10 and stone fruit by establishing an expiration date for these at the existing tolerance levels of 0.03 ppm and 0.05 ppm, respectively, to allow these tolerances to remain in effect for a period of 6 months after the effective date of this final rule. After the 6-month period expires, the allowable residues on members of the citrus fruit group 10-10 and the stone fruit group 12-12 must conform to the new lower tolerance level of 0.01 ppm. This reduction in tolerance level is not discriminatory; the same food safety standard contained in the FFDCA applies equally to domestically produced and imported foods. The new tolerance levels are supported by available residue data.

V. Conclusion

Therefore, tolerances are established for residues of fluazifop-P-butyl in or on berry, low growing, subgroup 13-07G at 3 ppm; Brassica, leafy greens, subgroup 4-16B at 15 ppm; chives, dried leaves at 40 ppm; chives, fresh leaves at 4 ppm; fruit, citrus, group 10-10 at 0.01 ppm; fruit, stone, group 12-12 at 0.01 ppm; leaf petiole vegetable subgroup 22B at 3 ppm; onion, green, subgroup 3-07B at 1.5 ppm; papaya at 0.01 ppm; and vegetable, Brassica, head and stem, group 5-16 at 30 ppm. The established tolerances for fruit, citrus, group 10 at 0.03 ppm and fruit, stone at 0.05 ppm are designated to expire 6 months from the publication of this document. EPA is removing the established tolerances for onion, green at 1.5 ppm; rhubarb at 0.50 ppm; and strawberry at 3.0 ppm as unnecessary upon the establishment of the new tolerances. In addition, EPA is revising the residue definition for fluazifop-P-butyl in both 40 CFR §180.411(a) and (c) to be consistent with Agency practice and to read as follows:

“Tolerances are established for residues of the herbicide fluazifop-P-butyl, butyl (2*R*)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, including its metabolites and degradates, in or on the commodities listed below. Compliance with the tolerance levels specified below is to be determined by measuring only those fluazifop-P-butyl residues convertible to fluazifop, 2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, expressed as fluazifop, in or on the commodity”.

Additionally, tolerances are established for indirect or inadvertent residues of the fluazifop-P-butyl metabolite, 5-trifluoromethyl-2-pyridinone (TFP) in or on corn, field, forage at 0.01 ppm; corn, field, grain at 0.01 ppm; and corn, field, stover at 0.015 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides, and pests, Reporting and recordkeeping requirements.

Dated: April 24, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Revise § 180.411 to read as follows:

§ 180.411 Fluazifop-P-butyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide fluazifop-P-butyl, butyl (2*R*)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, including its metabolites and degradates, in or on the commodities in table 1 to this paragraph (a). Compliance with the tolerance levels specified in table 1 is to be determined by measuring only those fluazifop-P-butyl residues convertible to fluazifop, 2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, expressed as fluazifop, in or on the commodity”.

Table 1 to Paragraph (a)

Commodity	Parts per million
Banana	0.01
Beans, dry, seed	50
Beet, sugar, dried pulp	1.0
Beet, sugar, molasses	3.5
Beet, sugar, roots	0.25
Berry, low growing, subgroup 13-07G	3
Brassica, leafy greens, subgroup 4-16B	15
Bushberry subgroup 13-07B	0.30
Caneberry subgroup 13-07A	0.08
Carrot, roots	2.0
Cattle, fat	0.05
Cattle, meat	0.05
Cattle, meat byproducts	0.05
Chives, dried leaves	40
Chives, fresh leaves	4
Citrus, dried pulp	0.40
Citrus, juice	0.06
Citrus, oil	30.0
Cotton, gin byproducts	1.5
Cotton, refined oil	1.3

Cotton, undelinted seed	1.0
Egg	0.05
Endive	6.0
Fruit, citrus, group 10 ²	0.03
Fruit, citrus, group 10-10	0.01
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13–07F	0.03
Fruit, stone ²	0.05
Fruit, stone, group 12-12	0.01
Goat, fat	0.05
Goat, meat	0.05
Goat, meat byproducts	0.05
Hog, fat	0.05
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	0.05
Horse, meat	0.05
Horse, meat byproducts	0.05
Leaf petiole vegetable subgroup 22B	3
Lettuce, head	3.0
Lettuce, leaf	5.0
Milk	0.05
Nut, macadamia	0.1
Onion, bulb, subgroup 3–07A	0.50
Onion, green, subgroup 3-07B	1.5
Papaya	0.01
Peanut	1.5
Peanut, meal	2.2
Pecans	0.05
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat byproducts	0.05
Potato ¹	1.0
Potato, chips ¹	2.0
Potato, granules/flakes ¹	4.0
Sheep, fat	0.05
Sheep, meat	0.05
Sheep, meat byproducts	0.05
Soybean, seed	2.5
Vegetable, Brassica, head and stem, group 5-16	30
Vegetable, tuberous and corm, except potato, subgroup 1D	1.5

¹ No U.S. registrations.

² This tolerance expires on [INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

(b) [Reserved]

(c) *Tolerances with regional registrations.* Tolerances are established for residues of the herbicide fluzifop-P-butyl, butyl (2*R*)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, including its metabolites and degradates, in or on the commodities in table 2 to this paragraph (c). Compliance with the tolerance levels specified in table 2 is to be determined by measuring only those fluzifop-P-butyl residues convertible to fluzifop, 2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid, expressed as fluzifop, in or on the commodity”.

Table 2 to Paragraph (c)

Commodity	Parts per million
Asparagus	3.0
Coffee, bean	0.1
Fescue, forage	4.0
Fescue, hay	15
Pepper, tabasco	1.0

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of the herbicide fluzifop-P-butyl, butyl (2*R*)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate, including its metabolites and degradates, in or on the commodities in table 3 to this paragraph (d). Compliance with the tolerance levels specified in table 3 is to be determined by measuring only those fluzifop-P-butyl residues convertible to 5-trifluoromethyl-2-pyridinone (TFP), expressed as TFP, in or on the commodity.

Table 3 to Paragraph (d)

Commodity	Parts per million
Corn, field, forage	0.01
Corn, field, grain	0.01
Corn, field, stover	0.015